UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:

BRISTOL-MYERS SQUIBB COMPANY CVR SECURITIES LITIGATION

21-CV-8255 (JMF)

OPINION AND ORDER

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JESSE M. FURMAN, United States District Judge:

A Contingent Value Right or "CVR" is "a security payable upon the occurrence of a specified future event." ECF No. 95 ("Compl."), ¶ 1. In 2019, as part of a merger, Bristol-Myers Squibb Company ("BMS") issued CVRs that were contingent on approval of three drugs by the Food and Drug Administration ("FDA") by specific deadlines. If the deadlines were met, BMS would have had to pay $6.4 billion to the holders of the CVRs. But the FDA approved one of the three drugs thirty-six days after its deadline. As a result, the CVRs expired worthless.

This litigation — a consolidated putative class action brought on behalf of those who purchased or otherwise acquired the BMS CVRs between November 20, 2019, and December 31, 2020 — followed. Plaintiffs allege that Defendants — BMS and a slew of current and former BMS executives and directors[1] — violated the Securities Act of 1933 (the "Securities Act"), the Securities Exchange Act of 1934 (the "Exchange Act"), and Securities and Exchange Commission ("SEC") Rules promulgated thereunder by making various statements regarding the

[1] The individual Defendants are: Chief Executive Officer Giovanni Caforio, Chief Financial Officer David V. Elkins, and Chief Medical Officer Samit Hirawat (together, the "Executive Defendants"); Lead Independent Director Vicki L. Sato and Directors Peter J. Arduini, Robert Bertolini, Matthew W. Emmens, Michael Grobstein, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Gerald L. Storch, and Karen H. Vousden (together, the "Board Defendants"); and former Chief Financial Officer Charles Bancroft and former Principal Accounting Officer Karen M. Santiago (together, the "Former Executive Defendants").

value of the CVRs and the likelihood of their being paid out. The premise of their claims is that Defendants intentionally delayed FDA approval to avoid the $6.4 billion payout.

Defendants now move, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, to dismiss the operative Consolidated Amended Class Action Complaint (the "Complaint"). For the reasons that follow, Defendants' motion must be and is GRANTED.

BACKGROUND

The following facts, taken from the Complaint, documents it incorporates, and matters of which the Court may take judicial notice, are construed in the light most favorable to Plaintiffs. *See, e.g.*, *Kleinman v. Elan Corp., PLC*, 706 F.3d 145, 152 (2d Cir. 2013); *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (stating that a court may consider "legally required public disclosure documents filed with the SEC").

A. The BMS-Celgene Merger

BMS is a publicly traded global pharmaceutical company. Compl. ¶ 44. On January 2, 2019, BMS entered into a preliminary merger agreement with Celgene Corporation ("Celgene"), another pharmaceutical company, pursuant to which each share of Celgene common stock would be exchanged for one share of BMS common stock, fifty dollars in cash, and one CVR. *Id.* ¶ 85; *see* ECF No. 101-1 ("Joint Proxy"), at 3. According to the agreement, the CVRs would trade on a stock exchange and would pay out nine dollars per CVR — $6.4 billion in total — but *only if* three drugs that Celgene had been developing, Liso-cel, Ide-cel, and Ozanimod (together, the "Milestone Drugs"), were approved by the FDA by certain deadlines: (1) Liso-cel by December 31, 2020; (2) Ozanimod by December 31, 2020; and (3) Ide-cel by March 31, 2021 (together, the "Milestone Deadlines"). Compl. ¶¶ 81, 87; *see also* Joint Proxy 4, 217-21. If even *one* Milestone Drug was approved *one day* late, the CVRs would expire worthless. *See* Compl. ¶ 81.

Celgene's shareholders voted to approve the merger on April 12, 2019. *Id.* ¶ 90. On November 20, 2019, the merger (the "Merger") closed and the CVRs were issued. *Id.* ¶ 95.

B. BMS Misses the Milestone Deadline for Liso-Cel

Liso-cel is a "biologic drug," *see* ECF No. 105 ("Pls.' Opp'n"), at 4; Compl. ¶ 91, meaning it is composed of natural and biological substances (such as "sugars, proteins, [] nucleic acids[,] or . . . cells and tissues"), FDA, *What Are "Biologics" Questions and Answers*, *available at* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers. As a result, Liso-cel could be approved only after the FDA had "reviewed [its Biologics License Application ('BLA')], conducted facility inspections [of where it will be manufactured,] and concluded that [it] is efficacious, safe[,] and appropriately labeled." Compl. ¶ 91. The BLA is the core of the application process and "must include, among other things, clinical data demonstrating the safety and efficacy of the therapy, information concerning the manufacturing and controls for production, a detailed description of the manufacturing facility[,] and the proposed product label." *Id.*

Celgene submitted the initial portion of Liso-cel's BLA to the FDA before the Merger. *Id.* On December 18, 2019, less than one month after the Merger, BMS submitted the final — and most important — portion of the BLA, titled "Chemistry, Manufacturing, and Controls" ("CMC") to the FDA. *Id.* ¶ 96. The FDA requires this module to include "a full description of the [biologic drug's] manufacturing process, including analytical procedures that demonstrate . . . prescribed standards of identity, quality, safety, purity, and potency and . . . substantiating data . . . [that] establish that the analytical procedures used in testing meet proper standards of accuracy, sensitivity, specificity, and reproducibility and are suitable for their intended purpose." *Id.* ¶ 20. On February 13, 2020, Liso-cel's application was granted "Priority Review" by the

FDA, which set its target approval date as August 17, 2020, about four-and-a-half months before the drug's December 31, 2020 Milestone Deadline. *Id.* ¶¶ 97-98.

On March 23, 2020, shortly after the start of the COVID-19 pandemic, however, the FDA directed BMS to supplement its CMC submission with "basic data" regarding Liso-cel's safeness and efficacy. *Id.* ¶¶ 99-100. BMS submitted an amended CMC to the FDA about three weeks later. *Id.* ¶ 100. After reviewing the submission, the FDA concluded that the supplemental information was a "Major Amendment" to Liso-cel's BLA, automatically triggering a three-month extension of Liso-cel's target approval date to November 16, 2020. *Id.* ¶¶ 101-02.

But that date was not to be either. Due to FDA scheduling issues and the Major Amendment designation, the FDA's inspections of the two manufacturing facilities slated to produce Liso-cel were not completed until early December 2020, only weeks before the Liso-cel Milestone Deadline. *Id.* ¶¶ 103, 120. The FDA found multiple regulatory violations at both facilities, which required BMS to respond with remediation plans. *Id.* ¶¶ 107-12, 116-24. BMS fully responded by the FDA's mandated deadline of December 23, 2020, *id.* ¶ 126; Pls.' Opp'n 12, but FDA approval of Liso-cel did not come until February 5, 2021, roughly five weeks after the December 31, 2020 Milestone Deadline, Compl. ¶¶ 33, 128. Accordingly, and notwithstanding the timely approvals of both Ozanimod and Ide-cel, the CVRs expired worthless. *Id.* ¶¶ 33, 128.

C. Plaintiffs' Claims

Plaintiffs in this case bring securities fraud claims under Sections 10(b), 14(a), and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b), 78n(a), 78t(a); SEC Rules 10b-5 ("Rule 10b-5") and 14a-9 ("Rule 14a-9"), 17 C.F.R. §§ 240.10b-5, 240.14a-9; and Sections 11, 12(a)(2), and 15 of

the Securities Act, 15 U.S.C. §§ 77k, 77*l*(a)(2), 77o.[2] Their claims arise from two sets of statements by Defendants "concerning the 'diligent' efforts [BMS] would make to meet the Milestone[Deadlines], the likelihood that the Milestone[Deadlines] would be met, and the purported value of the CVRs," Compl. ¶ 8: (1) statements made prior to the Merger (and thus before the CVRs were issued) in the February 22, 2019 Joint Proxy filed with the SEC, *see id.* ¶¶ 156-65, and a November 7, 2019 Guggenheim Partners analyst report about the Merger, *see id.* ¶¶ 166-67;[3] and (2) statements made after the Merger (and thus during the lifetime of the CVRs) in presentations, press releases, earnings calls, and SEC filings between December 8, 2019, and November 16, 2020, *see* Compl. ¶¶ 169-207. Plaintiffs' claims are all premised on the same theory: that, "all [the] while," Defendants "secretly slow-rolled the Liso-cel approval process so [BMS] could avoid the $6.4 billion CVR payout." Pls.' Opp'n 3.

LEGAL STANDARD

In reviewing a motion to dismiss pursuant to Rule 12(b)(6), a court must accept the factual allegations set forth in the complaint as true and draw all reasonable inferences in favor

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[2] This is not the only case that arose from expiration of the BMS CVRs. In a related case, also pending before this Court, the CVR Agreement trustee sues BMS for breach of contract by failing to use "diligent efforts" to meet the Milestone Deadlines. *See UMB Bank, N.A. v. Bristol-Myers Squibb Co.*, No. 21-CV-4897 (JMF) (S.D.N.Y. filed June 3, 2021). And in another case, removed from state court to this Court and then remanded, a CVR holder sued BMS for making false and misleading statements in a Registration Statement filed with the SEC in connection with the CVRs. *See Williams v. Bristol-Myers Squibb Co.*, No. 21-CV-9998 (JMF), 2022 WL 4345564 (S.D.N.Y. Sept. 19, 2022).

[3] The Joint Proxy, filed with the SEC on February 22, 2019, was included in BMS's Form S-4 Registration Statement, which was filed on February 1, 2019, and later amended on February 20, 2019. *See* Bristol-Myers Squibb Co., Registration Statement (Form S-4) (Feb. 1, 2019), *available at* https://www.sec.gov/Archives/edgar/data/14272/000114036119002181/s002620x1_s4.htm; Bristol-Myers Squibb Co., Amendment No. 2 to the Registration Statement (Form S-4/A) (Feb. 20, 2019), *available at* https://www.sec.gov/Archives/edgar/data/14272/000114036119003503/s002620x3_s4a.htm. For convenience, the Court refers to the Joint Proxy and Registration Statement together simply as "the Joint Proxy."

of the plaintiff. *See Giunta v. Dingman*, 893 F.3d 73, 79 (2d Cir. 2018). A court will not dismiss any claims unless the plaintiff has failed to plead sufficient facts to state a claim to relief that is facially plausible, *see Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) — that is, one that contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged," *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). More specifically, the plaintiff must allege facts showing "more than a sheer possibility that a defendant has acted unlawfully." *Id.* A complaint that offers only "labels and conclusions" or "a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Further, if the plaintiff "ha[s] not nudged [its] claims across the line from conceivable to plausible, [those claims] must be dismissed." *Id.* at 570.

DISCUSSION

As noted above, Plaintiffs bring claims under both the Exchange Act and the Securities Act. Defendants advance various arguments in support of dismissal of these claims, but the Court need only and does only address a few. First, the Court finds that Plaintiffs' claim under Section 10(b) of the Exchange Act and Rule 10b-5 fail because the Complaint does not adequately allege scienter. Second, the Court concludes that Plaintiffs' claims under the Securities Act, as well as their claims under Section 14(a) of the Exchange Act and Rule 14a-9, are shielded by the safe harbor provisions of the Private Securities Litigation Reform Act (the "PSLRA"), 15 U.S.C. § 77z-2(c) (Securities Act safe harbor); *id.* § 78u-5(c) (Exchange Act safe harbor). In the absence of a "primary" violation, it follows that Plaintiffs' "controlling person" claims also fail. The Court will address each of these defects in turn.

A. Section 10(b) and Rule 10b-5 Claim

First, Plaintiffs bring a claim under Section 10(b) of the Exchange Act and Rule 10b-5 against BMS and the Executive Defendants in connection with their alleged post-Merger misstatements. *See* Compl. ¶¶ 243-47. To state a claim under these provisions, a plaintiff must allege "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011) (internal quotation marks omitted); *accord Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204, 212 (2d Cir. 2020). Pursuant to the PSLRA, 15 U.S.C. § 78u-4(b)(2), a plaintiff alleging securities fraud based on misleading statements or omissions must "'demonstrate with specificity why and how' each statement is materially false or misleading." *In re AstraZeneca PLC Sec. Litig.*, 21-CV-722 (JPO), 2022 WL 4133258, at *6 (S.D.N.Y. Sept. 22, 2022) (quoting *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004)). A plaintiff must show, moreover, that the "misstatement was false *at the time it was made*." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 571 (S.D.N.Y. 2014) (citing *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos., Inc.*, 75 F.3d 801, 812-13 (2d Cir. 1996)).

Significantly, the PSLRA also requires that a plaintiff plead scienter — that is, the defendant's "intention to deceive, manipulate, or defraud" — with particularity. *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 313 (2007) (internal quotation marks omitted). To satisfy that requirement, a complaint must, with respect to each defendant and "'with respect to each act or omission alleged to [constitute securities fraud], state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *ATSI*

Commc'ns, 493 F.3d at 99 (quoting 15 U.S.C. § 78u-4(b)(2)); *see, e.g.*, *City of Omaha Police & Fire Ret. Sys. v. Evoqua Water Techs. Corp.*, 450 F. Supp. 3d 379, 419 (S.D.N.Y. 2020) ("[I]n a case involving multiple defendants, [the] plaintiffs must plead circumstances providing a factual basis for scienter for each defendant . . . ." (cleaned up)); *In re Lions Gate Ent. Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 22 (S.D.N.Y. 2016) (noting that a plaintiff must "allege facts supporting a strong inference with respect to *each* defendant" (emphasis added)). The "strong inference" must be "more than merely plausible or reasonable." *Tellabs*, 551 U.S. at 314. The necessary inquiry is "inherently comparative." *Id.* at 323. That is, the Court "must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 324. A complaint alleging securities fraud will survive "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.*

In this Circuit, a plaintiff may satisfy the scienter pleading requirement in either of two ways: "by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns*, 493 F.3d at 99. The former requires a plaintiff to allege that the defendant "benefitted in some concrete and personal way from the purported fraud." *ECA, Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009) (internal quotation marks omitted). The latter requires allegations of either actual intent or "conscious recklessness — *i.e.*, a state of mind approximating actual intent, and not merely a heightened form of negligence." *Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 106 (2d Cir. 2015) (internal quotation marks omitted). More specifically, a plaintiff must allege, "at the least," that the defendant engaged in "conduct which is highly unreasonable and which

represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (internal quotation marks omitted). As a general matter, courts have approved of claims based on recklessness when plaintiffs "have specifically alleged defendants' knowledge of facts or access to information contradicting their public statements." *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000). "Under such circumstances," the reasoning goes, "defendants knew or, more importantly, should have known that they were misrepresenting material facts related to the corporation." *Id.*

Measured against these standards, Plaintiffs' allegations of scienter fall short.

1. Motive and Opportunity

First, Plaintiffs' arguments with respect to the motive-and-opportunity prong of the scienter test fall short because they fail to allege that any of the Executive Defendants "benefitted in some concrete and personal way from the purported fraud." *ECA*, 553 F.3d at 198; *see, e.g.*, *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) ("[I]t is not sufficient to allege goals that are possessed by virtually all corporate insiders . . . ." (internal quotation marks omitted)). Alleging that the Executive Defendants had a motive "to avoid the massive $6.4 billion payout . . . to the CVR holders," Pls.' Opp'n 18, Plaintiffs place much weight on the "massive" size of the alleged fraud, *see, e.g.*, Compl. ¶¶ 3, 7, 130, 132; Pls.' Opp'n 13, 18 (citing *In re Salix Pharmaceuticals, Ltd.*, No. 14-CV-8925 (KMW), 2016 WL 1629341, at *16 & n.15 (S.D.N.Y. Apr. 22, 2016)).[4] In doing so, however, they ignore that "the size of the fraud alone does not create an inference of scienter." *City of Birmingham Firemen's &*

[4] Like other courts, the court in *Salix Pharmaceuticals* considered the size of the fraud in connection with its analysis of the conscious misbehavior or recklessness theory of scienter, not motive and opportunity. Plaintiffs here, however, argue the point in relation to motive.

Policemen's Supplemental Pension Sys. v. Ryanair Holdings PLC, No. 18-CV-10330 (JPO), 2020 WL 2834857, at *5 (S.D.N.Y. June 1, 2020). *Salix Pharmaceuticals*, on which Plaintiffs rely, is not to the contrary. In fact, the court in *Salix Pharmaceuticals* explicitly held that a plaintiff "*cannot* plead scienter based *solely* on the magnitude of the fraud" and that the magnitude of a fraud can *only* "buttress" other allegations of scienter. 2016 WL 1629341,at *16 (initial emphasis added). Here, there are no other allegations to "buttress" and so the size of the fraud alone does not cut it.

Plaintiffs also argue that the Executive Defendants were motivated by the potential "increases in the value of their millions of dollars' worth of [BMS] common stock," Pls.' Opp'n 19; *see also* Compl. ¶¶ 151, 221, if BMS did not have to pay out the CVRs. But the compensation packages at issue were announced *months* after the Merger and after the CVRs were issued. *Compare* Compl. ¶ 95, *with id.* ¶ 143. Moreover, "maintain[ing] a high stock price in order to increase executive compensation" is a paradigmatic objective "generally possessed by most corporate directors and insiders" and thus does not suffice. *S. Cherry St., LLC*, 573 F.3d at 109; *Kalnit*, 264 F.3d at 139. If anything, the absence of any allegation that the Executive Defendants purchased additional shares of BMS stock during the lifespan of the CVRs undermines Plaintiffs' allegations, as the gravamen of those allegations is that the Executive Defendants knew, "all [the] while," that the Milestone Deadlines would be missed and, thus, that the market was underpricing BMS stock. Pls.' Opp'n 3, 19-20; *see, e.g.*, *In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000) ("The absence of . . . any . . . evidence of pecuniary gain by company insiders at shareholders' expense[] is inconsistent with an intent to defraud shareholders.").

Finally, Plaintiffs point to the "atypical all-or-nothing CVR payout structure" and the fact that BMS "refus[ed] to buy back any CVRs on the open market . . . [when] the CVRs were trading well below the $9 payout." Pls.' Opp'n 18. But Plaintiffs do not allege that the merger agreement between BMS and Celgene (which contained the CVR payout structure) was not negotiated at arms-length or otherwise fraudulently induced. Instead, the parties to the agreement, and their shareholders, knowingly agreed to the CVR payout structure. Compl. ¶¶ 87, 89. (Needless to say, Plaintiffs also had notice of the allegedly "atypical" payout structure when they chose to keep or acquire the CVRs.) Meanwhile, Plaintiffs' argument that BMS's refusal to buy back CVRs on the open market is indicative of scienter is unpersuasive. For one thing, there are alternative explanations for the refusal that are arguably more "cogent" and "compelling" than the inference Plaintiffs urge: that BMS was worried about the appearance of impropriety given the asymmetrical information balance between the company and the CVR holders, *see* ECF No. 100 ("Defs.' Mem."), at 32 n.15; and that BMS, even without the plot that Plaintiffs allege, believed that the risks of buying back the CVRs outweighed any potential benefits.[5] For another, Plaintiffs do not cite, and the Court has not found, any authority supporting Plaintiffs' argument — while there is authority rejecting it. *See, e.g.*, *Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 338 (S.D.N.Y. 2011) ("[P]laintiff cannot identity a single case holding that . . . a corporation's failure to purchase [its securities] during the class period . . . is sufficient to establish motive. Nor can the Court find a case supporting this argument.").

[5] When the CVRs were issued, BMS reported that the probability of the Milestone Deadlines being met was only 45% — which is to say that, *at their inception*, the probability of the CVRs expiring worthless was put at 55%. Joint Proxy 157.

2. Strong Circumstantial Evidence of Conscious Misbehavior or Recklessness

Whether Plaintiffs' allegations are sufficient to establish scienter through a showing of strong circumstantial of conscious misbehavior or recklessness is a closer question, but the answer is ultimately the same. Notably, where, as here, "there is no evidence of motive, . . . the strength of the circumstantial allegations [of scienter] must be correspondingly greater." *Marcu v. Cheetah Mobile, Inc.*, No. 18-CV-11184 (JMF), 2020 WL 4016645, at *7 (S.D.N.Y. July 16, 2020) (internal quotation marks omitted). This is a "demanding requirement[]," *id.*, and one that Plaintiffs do not meet.

Plaintiffs' argument as to conscious misbehavior or recklessness is premised on BMS having allegedly made ten missteps during the Liso-cel approval process, including delays in filing and supplementing information with the FDA and not adequately preparing the two Liso-cel manufacturing facilities for their inspections. *See* Pls.' Opp'n 11-13. "[I]t is simply implausible," Plaintiffs contend, "that these ten events all happened in such a way as to delay the FDA approval of Liso-cel just enough to save [BMS] $6.4 billion, accidentally." Pls.' Opp'n 13 (emphasis omitted). But that contention is a strawman argument. The relevant issue is not whether the alleged missteps occurred or even whether they suggest a deliberate plan to miss the Milestone Deadline for Lis-cel. Instead, the relevant question is whether the allegations in the Complaint support an inference that the Executive Defendants *knew* (or should have known) of the alleged missteps. They do not. In fact, Plaintiffs do not identify even *one* instance in which an Executive Defendant is alleged to have knowledge of one of the purported missteps. *See, e.g.*, Defs.' Mem. 34 ("There is no allegation that *any* of the defendants was aware of the alleged operational issues at [the manufacturing facilities]."); *see also* Compl. ¶ 112 (explaining that BMS "knew or should have known" of the alleged issues at the manufacturing facilities but

failing to attribute this knowledge to any Executive Defendant). All Plaintiffs can point to is a single sentence in the Guggenheim Partners analyst report stating that "[BMS] Management emphasized [to analysts at Guggenheim Partners] several points, including [that] oversight of the CVR is a board-level responsibility." *E.g.*, Compl. ¶ 92 (emphasis omitted); *see* Pls.' Opp'n 20. But "generalized allegations about . . . management [that do] not implicat[e] any of the named Defendants . . . are insufficient to support an inference of scienter." *City of Omaha Police & Fire Ret. Sys.*, 450 F. Supp. 3d at 422.[6]

Plaintiffs' reliance on the opinions of an "FDA Biologics Expert," *see, e.g.*, Compl. ¶¶ 20, 96, 100, 116; *see also id.* ¶ 4 & n.1 (describing the FDA Biologics Expert), and information from eight confidential witnesses, *see, e.g.*, *id.* ¶¶ 101, 106, 120, 121, 123; *see also id.* app. A (describing the confidential witnesses), does not get them across the line either.[7] The confidential witnesses shed no light on the scienter of the Executive Defendants; indeed, none of them are alleged to have ever interacted with any Executive Defendant regarding Liso-cel. *See Long Miao v. Fanhua, Inc.*, 442 F. Supp. 3d 774, 779 n.19 (S.D.N.Y. 2020) ("[W]here a complaint relies on information from a [confidential witness] to establish scienter, the complaint must describe the nature of the [confidential witness's] contact with the individual defendants that would be probative of [the] defendants' mental state."); *Campo v. Sears Holding Corp.*, 635

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[6] Plaintiffs argue that their "alleg[ations] that [BMS's] top management repeatedly made false or misleading statements" is also probative of scienter. Pls.' Opp'n 20-21. This circular argument is without merit. *See, e.g.*, *In re Lions Gate Ent. Corp. Sec. Litig.*, 165 F. Supp. 3d at 24 ("[A]lleging that [statements] were incomplete or that they omitted material information[] is not enough to plead scienter based on conscious misbehavior or recklessness.").

[7] The parties spill much ink on whether or to what extent the Court may consider the FDA Biologics Expert's opinions or information from the confidential witnesses. *Compare* Defs.' Mem. 17, *and* ECF No. 106 ("Defs.' Reply"), at 13-14, *with* Pls.' Opp'n 14-16 & n.11. The Court need not and does not resolve these disputes as it would not affect the Court's analysis.

F. Supp. 2d 323, 335 (S.D.N.Y. 2009) (finding no scienter where the confidential witnesses cited in the complaint are not alleged to have interacted with the defendants), *aff'd*, 371 F. App'x 212 (2d Cir. 2010). The FDA Biologics Expert does allege that certain FDA requirements "would have been familiar to any pharmaceutical executive who was responsible for submitting biologics to the FDA for approval," "would have been well known to multitudes of people working at [BMS]," and "would be familiar to . . . [BMS's] Head of Regulatory Affairs and Head of Product Quality." *E.g.*, Compl. ¶¶ 20, 30. But these allegations are not relevant to the Executive Defendants' knowledge either. Moreover, it is well established that an expert may not opine on the state of mind or knowledge of a party. *See, e.g.*, *Anderson News, L.L.C. v. Am. Media, Inc.*, No. 09-CV-2227 (PAC), 2015 WL 5003528, at *2 (S.D.N.Y. Aug. 20, 2015), *aff'd*, 899 F.3d 87 (2d Cir. 2018); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 479 (S.D.N.Y. 2016).

Finally, Plaintiffs rely on the assertion that FDA approval for the Target Drugs was essential to BMS. *See* Pls.' Opp'n 20-22. At bottom, that argument sounds in the "core operations doctrine," which "permits an inference that a company and its senior executives have knowledge of information concerning the 'core operations' of a business" and, by extension, knew or should have known whether statements concerning such "core operations" were false or misleading. *Hensley v. IEC Elecs. Corp.*, No. 13-CV-4507 (JMF), 2014 WL 4473373, at *5 (S.D.N.Y. Sept. 11, 2014) (internal quotation marks omitted). But it is far from clear that the core operations doctrine remains valid in light of the PSLRA. *See, e.g.*, *City of Omaha Police & Fire Ret. Sys.*, 450 F. Supp. 3d at 423-24 ("It remains unresolved in the Second Circuit whether the core-operations doctrine survived the passage of the PSLRA, and many courts have expressed doubts as to the doctrine's continuing import." (cleaned up)). At best, core-operations

allegations are "supplementary" — that is, they are not "independently sufficient means to plead scienter." *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 353 (S.D.N.Y. 2011); *see also Marcu*, 2020 WL 4016645, at *8. And in any event, "[w]hen applying the doctrine, courts have required that the operation in question constitute nearly all of a company's business before finding scienter." *Frankfurt-Tr. Inv. Lux. AG v. United Techs. Corp.*, 336 F. Supp. 3d 196, 225 (S.D.N.Y. 2018) (cleaned up). In this case, Plaintiffs do not allege — nor is it likely they could plausibly allege — that approval of Liso-cel "constitute[d] nearly all of [BMS's] business." *Id.*; *see, e.g.*, *Tyler*, 814 F. Supp. 2d at 343-44.

In any event, even if a plaintiff is able to make a showing of strong circumstantial evidence, a court "must [then] ask . . . '[W]ould a reasonable person deem the inference of scienter at least as strong as any opposing inference?'" *ECA*, 553 F.3d at 198 (quoting *Tellabs*, 551 U.S. at 326). The PSLRA's scienter requirement met only if the answer to this question is "yes." Here, "consider[ing] both the inferences urged by [Plaintiffs] and . . . competing inferences rationally drawn from all the facts alleged, taken collectively," *id.*, the answer is no. In whole, the more compelling inference to be drawn from the pleaded facts is that both BMS and the FDA experienced embarrassing, but not "extreme" setbacks during an unprecedented pandemic. *Rothman v. Gregor*, 220 F.3d 81, 90 (2d Cir. 2000); *see* Defs.' Mem. 32-33. Plaintiffs point to the fact that the FDA approved other drugs during the pandemic in 2020 to argue that this was not the case. *See, e.g.*, Compl. ¶¶ 138-40, 153, 220; *see also* Pls.' Opp'n 17. But that argument is without merit for several reasons. First, it overlooks the fact that the FDA *did* approve Liso-cel during the pandemic and only a few weeks after its target approval date. Second, without knowing the particulars of the other drugs approved by the FDA during the pandemic, it is impossible to know whether Plaintiffs are comparing apples and apples or apples

and oranges. Third, the fact that the *FDA* approved other drugs during the pandemic says nothing about whether *BMS's* alleged missteps were attributable in part to the pandemic. And finally, how the FDA handled other approvals during the pandemic has no bearing on Defendants' actions and knowledge — Defendants did not determine the FDA's priorities and how it should deploy its resources during the pandemic. In the final analysis, the Liso-cell setbacks are more attributable to corporate (or government agency) "mismanagement," which does not, by itself, give rise to a strong inference of scienter. *Fries v. N. Oil & Gas, Inc.*, 285 F. Supp. 3d 706, 721 (S.D.N.Y. 2018).

For the foregoing reasons, the Court concludes that Plaintiffs' allegations fall short of establishing that the Executive Defendants acted with the requisite scienter. The Court reaches the same conclusion with respect to BMS itself. It is true that allegations of corporate scienter may be sufficient even when a plaintiff is unable to specify individuals who knew of the facts concealed. *See, e.g.*, *Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) ("[I]t is possible to raise the required inference with regard to a corporate defendant without doing so with regard to a specific individual defendant."). But here, the Complaint "fail[s] to 'create a strong inference either (1) that someone whose intent could be imputed to [BMS] acted with the requisite scienter or (2) that the [alleged misstatements] would have been approved by corporate officials sufficiently knowledgeable about [BMS] to know that those statements were misleading.'" *Town of Davie Police Officers Ret. Sys. v. City of N. Mia. Beach Police Officers' & Firefighters' Ret. Plan*, No. 21-909-CV, 2021 WL 5142702, at *3 (2d Cir. Nov. 5, 2021) (summary order) (quoting *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 177 (2d Cir. 2015)).

Accordingly, Plaintiffs' Section 10(b) and Rule 10b-5 claim must be and is dismissed for failure to adequately allege scienter.

B. Securities Act Claims

Plaintiffs' primary Securities Act claims are brought against BMS, the Board Defendants, the Former Executive Defendants, and Caforio under Sections 11 and 12(a)(2) of the Act. *See* Compl. ¶¶ 262-82. Section 11 provides that any signatory to a registration statement, director of the issuer, or underwriter, may be held liable to purchasers of registered securities if the registration statement is materially misleading. *See Tongue v. Sanofi*, 816 F.3d 199, 209 (2d Cir. 2016). More specifically, "[t]o state a claim under Section 11, [a] plaintiff must allege that: (1) [it] purchased a registered security, either directly from the issuer or in the aftermarket following the offering; (2) the defendant participated in the offering in a manner sufficient to give rise to liability under section 11; and (3) the registration statement 'contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.'" *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 358-59 (2d Cir. 2010) (quoting 15 U.S.C. § 77k(a)). Section 12(a)(2), on the other hand, imposes liability for selling or offering securities with a prospectus (e.g., the Joint Proxy here) that "includes an untrue statement of a material fact or omits to state a material fact necessary in order to make the statements, in light of the circumstances under which they were made, not misleading (the purchaser not knowing of such untruth or omission)." 15 U.S.C. § 77*l*(a)(2). Courts regularly analyze claims brought under Sections 11 and 12(a)(2) together, as they are "siblings with roughly parallel elements." *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d at 359; *accord In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d at 368.

Significantly, the PSLRA contains a "safe harbor" that shields forward-looking statements from liability under the Securities Act. *See* 15 U.S.C. § 77z-2.[8] Under the safe harbor provision, a "forward-looking statement" is defined to include "a statement containing a projection of revenues . . . or other financial items," "a statement of the plans and objectives of management for future operations," or "a statement of future economic performance." *Id.* §§ 77z-2(i)(1)(A)-(C); *see, e.g.*, *In re Barrick Gold Corp. Sec. Litig.*, 341 F. Supp. 3d 358, 375-76 (S.D.N.Y. 2018) ("[A] statement that projects results in the future is [] forward-looking." (cleaned up)). Such statements are not actionable if (1) they are "identified and accompanied by meaningful cautionary language," (2) they are "immaterial," or (3) "the plaintiff fails to prove that [the forward-looking statement at issue] was made with actual knowledge that it was false or misleading." *Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010); *see also, e.g.*, *In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 245-46 (2d Cir. 2016) (noting that forward-looking statements are shielded by the PSLRA safe harbor "if *any* of the [provision's] three prongs applies" (emphasis added)). Defendants argue that Plaintiffs' Securities Act claims based on the Joint Proxy are all barred by the PSLRA's safe harbor provision. *See* Defs.' Mem. 14-18.[9] The Court agrees.

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[8] The PSLRA contains a safe harbor applicable to claims under the Exchange Act that is substantively identical. *Compare* 15 U.S.C. § 77z-2(c) (Securities Act), *with id.* § 78u-5(c) (Exchange Act). In light of that, courts frequently consider the two safe harbors together. *See, e.g.*, *In re SunEdison, Inc. Sec. Litig.*, 300 F. Supp. 3d 444, 464-66 (S.D.N.Y. 2018). Accordingly, in the discussions that follow, the Court relies on cases under both provisions. *See generally Gorss Motels, Inc. v. Lands' End, Inc.*, 997 F.3d 470, 478 (2d Cir. 2021) ("[W]hen Congress uses the same words in two different portions of the same statute, we presume that they have the same meaning in both.").

[9] In their Complaint, Plaintiffs also rest their Securities Act claims on an analyst report prepared by Guggenheim Partners. *See* Compl. ¶¶ 166-67. But as Defendants note, and Plaintiffs do not dispute, an analyst report is neither a "registration statement" nor a "prospectus." Defs.' Mem. 21 n.9; Defs.' Reply 6. Nor is it an "oral communication[]" that "relate[s] to a prospectus." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 567-68 (1995). Thus,

First, the alleged misstatements in the Joint Proxy are plainly forward-looking within the meaning of the PSLRA. For example, statements such as

- "Celgene's key late-stage product candidates, which are *expected* to launch in 2019 and 2020 . . . ," Joint Proxy 20, 82 (emphasis added); *see also* Compl. ¶ 158,
- "[BMS] management provided *an estimate of the probability* of achieving the three FDA approvals . . . ," Joint Proxy 157 (emphasis added); *see also* Compl. ¶ 158,
- "Each CVR represents the right to receive a one-time cash payment . . . *if* the [FDA] . . . approves [the Target Drugs by the Milestone Deadlines]," Joint Proxy 4 (emphasis added); *see also* Compl. ¶ 160, and
- "[BMS] *has agreed to use* 'diligent efforts' . . . to achieve the CVR milestone." Joint Proxy 52 (emphasis added); *see also id.* at 219; Compl. ¶ 161,

all concern either "future economic performance" or "the plans and objectives of management for future operations," 15 U.S.C. §§ 77z-2(i)(1)(B)-(C). Moreover, courts in this District have consistently held that "statements about FDA approval" — many of statements at issue here — "are classically forward-looking" because "they address what defendants expect to occur in the future." *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 535 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *see also, e.g.*, *Schaeffer v. Nabriva Therapeutics PLC*, No. 19-CV-4183 (VM), 2020 WL 7701463, at *10 (S.D.N.Y. Apr. 28, 2020); *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333-34 (S.D.N.Y. 2014).

Plaintiffs' contention, made in passing, that the alleged misstatements are not forward-looking because they "relate to then-existing facts and conditions," Pls.' Opp'n 31, can be swiftly rejected. Plaintiffs' sole contemporaneous "fact" is that Defendants, at the time the Joint Proxy was issued, never intended for the FDA to approve Liso-cel by the Milestone Deadline. *Id.* But as Defendants argue in their reply brief, this argument "confuses the question of whether

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Plaintiffs cannot bring a claim based on the report under the Securities Act. *See, e.g.*, *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d at 358-59.

a statement is forward-looking with the applicability of the safe harbor's 'actual knowledge' prong." Defs.' Reply 2; *see, e.g.*, *In re NovaGold Res. Inc. Sec. Litig.*, 629 F. Supp. 2d 272, 292 (S.D.N.Y. 2009) (characterizing a similar argument as "better understood as an assertion that [the defendant] knew, based on present conditions, that the statements were false when made, and should not be protected by the PSLRA safe harbor"). Accepting Plaintiffs' argument would therefore "rip a large hole in [the PSLRA]," *In re Turquoise Hill Res. Ltd. Sec. Litig.*, — F. Supp. 3d —, 2022 WL 4085677, at *24 (S.D.N.Y. 2022) (internal quotation marks omitted), and result in an exception swallowing the rule. Tellingly, Plaintiffs cite only two district court decisions, both from other Circuits, to support their contention. *See* Pls.' Opp'n 27 (citing *In re Nuvelo, Inc. Securities Litigation*, 668 F. Supp. 2d 1217, 1230-31 (N.D. Cal. 2009), and *In re NPS Pharmaceuticals, Inc. Securities Litigation*, No. 06-CV-570 et al., 2007 WL 1976589, at *4 (D. Utah July 3, 2007)). But these decisions are obviously not binding on this Court and their reasoning has been widely rejected by other courts. *See, e.g.*, *Gray v. Wesco Aircraft Holdings, Inc.*, 454 F. Supp. 3d 366, 386-92 (S.D.N.Y. 2020) (rejecting similar arguments and citing cases), *aff'd*, 847 F. App'x 35 (2d Cir. 2021). In short, the Court concludes that the statements at issue are forward looking within the meaning of the PSLRA.

Second, the statements at issue are "identified and accompanied by meaningful cautionary language." *Slayton*, 604 F.3d at 766. Cautionary language is "meaningful" when it "convey[s] substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." *Id.* at 771. The statements at issue here plainly meet that standard as they are labeled as "forward-looking," *see, e.g.*, Joint Proxy 80-81, 158, and accompanied by an exhaustive and substantive description of potential risks, *see, e.g.*, *id.* at 50-52. For example, the Joint Proxy explicitly warns investors that they

"may not receive any payment on the CVRs" and that "the value, if any, of the CVRs, is speculative, and the CVRs may ultimately have no value." *Id.* at 50. The Joint Proxy goes on to state that achieving the Milestone Deadlines is dependent on "uncertainties relating to . . . the content and timing of decisions made by the FDA." *Id.* at 80. In fact, the Joint Proxy explicitly notes that the probability of BMS meeting the Milestone Deadlines was only 45%. *Id.* at 157. This language is not mere boilerplate warning of "certain risks and uncertainties." *Ill. State Bd. of Inv. v. Authentidate Holding Corp.*, 369 F. App'x 260, 264 n.3 (2d Cir. 2010) (summary order) (internal quotation marks omitted). Instead, it is "extensive and specific," substantive, and tailored to the risks involved. *Slayton*, 604 F.3d at 772-73 (internal quotation marks omitted). It is equally, if not more, cautionary than statements that other courts have found to be protected. *See, e.g.*, *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 535-36.

Plaintiffs' counterarguments are unpersuasive. They principally contend that the cautionary language was not meaningful because Defendants knew that the statements were false when they were made. *See* Pls.' Opp'n 32 ("Defendants offer a long list of instances of purportedly meaningful cautionary language, but none of these [sic] indicate Defendants planned to deliberately delay the FDA application process, nor do they convey that the then-actual value of the CVRs was $0."). In doing so, however, Plaintiffs once again conflate distinct provisions of the PSLRA's safe harbor — this time, the actual knowledge and meaningful cautionary language prongs of the statute. It is well established that "[*e*]*ither* cautionary language *or* an absence of knowledge is alone sufficient to trigger the safe harbor." *Gray*, 454 F. Supp. 3d at 395 (emphasis added). "If the Court were to accept" Plaintiffs' argument, "an allegation of actual knowledge of falsity would suffice to deprive a forward-looking statement of the

protections of safe harbor even if there were meaningful cautionary language otherwise. Such a result would be contrary to the disjunctive nature of the safe harbor elements." *Id.* at 394.

In sum, Plaintiffs fail to allege any misstatements that are actionable under the Securities Act. Thus, their Section 11 and 12(a)(2) claims must be and are dismissed.

C. Remaining Claims

Finally, Plaintiffs bring claims under Section 14(a) of the Exchange Act and Rule 14a-9, as well as "controlling person" claims under Section 20(a) of the Exchange Act and Section 15 of the Securities Act. Compl. ¶¶ 248-71, 283-91. To the extent that Plaintiffs' Section 14(a) and Rule 14a-9 claims are based on the Joint Proxy, they fail for the reasons that doomed their Securities Act claims, because, as noted above, the PSLRA contains a safe harbor provision that applies to claims under the Exchange Act. To the extent that the Section 14(a) and Rule 14a-9 claims are based on the Guggenheim Partners analyst report, they fail because the report is plainly not a "proxy statement." *See Bond Opportunity Fund v. Unilab Corp.*, 87 F. App'x 772, 773 (2d Cir. 2004) (summary order) ("In order to recover under Section 14(a) and Rule 14a-9, plaintiffs must show that [] a proxy statement contained a material misrepresentation or omission . . ."); *accord Gray*, 454 F. Supp. 3d at 384; *see also* 17 C.F.R. § 240.14a-3(a) (identifying a proxy statement as a certain type of document that is publicly filed with the SEC). Finally, Plaintiffs' "controlling person" claims must be and are dismissed because, for the reasons discussed above, they fail to plead a "primary violation" of either the Exchange Act or the Securities Act. *See, e.g.*, *Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co.*, 28 F.4th 343, 356-57 (2d Cir. 2022) (Section 20(a)); *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 173-74 (2d Cir. 2021) (Section 15).

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is GRANTED and Plaintiffs' claims are dismissed. That leaves only the question of whether Plaintiffs should be granted leave to amend the Complaint. Leave to amend a complaint should be freely given "when justice so requires," Fed. R. Civ. P. 15(a)(2), and complaints dismissed under the PSLRA "are almost always dismissed with leave to amend," *Pasternack v. Shrader*, 863 F.3d 162, 175 (2d Cir. 2017) (internal quotation marks omitted). That said, "[w]here it appears that granting leave to amend is unlikely to be productive, . . . it is not an abuse of discretion to deny leave to amend." *Ruffolo v. Oppenheimer & Co.*, 987 F.2d 129, 131 (2d Cir. 1993). Applying the foregoing standards, the Court denies leave to amend Plaintiffs' Securities Act and Section 14(a) and Rule 14a-9 claims because it is "unlikely to be productive." *Id.* By contrast, and notwithstanding the fact that Plaintiffs do not request leave to amend, the Court grants Plaintiffs leave to amend to address the deficiencies identified in their other claims. *See, e.g.*, *Loreley Fin. (Jersey) No. 3 Ltd.*, 797 F.3d at 190-91. Plaintiffs shall file any Second Amended Complaint **within thirty days of the date of this Opinion and Order**. The Clerk of Court is directed to terminate ECF No. 99.

SO ORDERED.

Dated: March 1, 2023
New York, New York

JESSE M. FURMAN
United States District Judge